# Repeatability and Reproducibility of Intraocular Pressure and Dynamic Corneal Response Parameters Assessed by the Corvis ST

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Abstract

PURPOSE: To assess the repeatability and reproducibility of dynamic corneal response parameters measured by the Corvis ST (Oculus, Wetzlar, Germany).

METHODS: One eye randomly selected from 32 healthy volunteers was examined by the Corvis ST. Three different Corvis ST devices were used in an alternated random order for taking three measurements at each device in each subject. Standard intraocular pressure (IOP) provided by the Corvis ST, the biomechanical compensated IOP (bIOP) and the dynamic corneal response parameters (DCR) were evaluated. An ANOVA model was used to assess the repeatability and reproducibility. It was built with random subject, random device and random interactions between subjects and device as factors. The within subject standard deviation (ζw) and coefficient of variation (CV) were assessed.

RESULTS: Regarding pressure indices, the ζw was bellow 1mmHg for repeatability (0.98 for IOP and 0.89 and bIOP), the CV was 6.6% for IOP and 6.1% for bIOP. For reproducibility the ζw was around 1mmHg (1.12 for IOP and 1.05 for bIOP), the CV was 7.6% for IOP and 7.1% and 2.9 for bIOP. Most of DCR indices presented CV for repeatability below 4%. The first applanation (A1) velocity and the stiffness parameter (SP) A1 had slightly higher CV 5.4% and 5%, respectively. For reproducibility the CV of most of the indices were bellow 6%. The deformation amplitude (DA) ratio in 1mm and Integrated Radius were below 4% (1.2% and 3.8%, respectively). A1 velocity and SP A1 were slightly higher (7.9% and 6.5%, respectively).

CONCLUSIONS:

The Corvis ST showed good precision (repeatability and reproducibility) for IOP measurements and for DCR in healthy eyes.

Corneal biomechanical assessment has an important role for the diagnosis and characterization of ocular diseases such as keratoconus, Fuch's dystrophy, and glaucoma.[1-3] Biomechanical fragility is also related to the susceptibility of the cornea for ectasia progression, which is an ultimate factor for assessing the risk for iatrogenic kerectasia after laser vision correction.[4-6] In addition, therapeutic manipulation of corneal biomechanics has been introduced as a treatment for ectatic corneal diseases,[7] and other ocular conditions such as presbyopia.[8]

*In vivo* corneal biomechanics assessment started in 2005 with the introduction of the Ocular Response Analyzer. (ORA; Reichert Ocular Instruments, Dephew, NY)[9]. The ORA combines an air puff with an infrared light emitter and receiver. This device only allows an indirect assessment of the corneal deformation based on the signal of the infrared light. The Corvis ST (Oculus Optikgeräte, Inc., Wetzlar, Germany) is a relatively new corneal biomechanics device, composed of an air puff indentation system and ultra-high-speed Scheimpflug technology. The camera has a blue light LED and acquires a sequence of 140 images of the deformation process at over 4330 frames/s with 8mm horizontal coverage. With this technology, it is possible to actually see how the cornea deforms in response to the air puff pressure.[10]

The new software of the Corvis ST provides new parameters based on corneal deformation.[11,12] The present study examines the repeatability and reproducibility of these new parameters in normal corneas.

## Methods

The study was conducted in healthy volunteers, conformed to the tenets of the Declaration of Helsinki and was approved by the ethical committee. The study included thirty two volunteers with normal ophthalmic examinations. Exclusion criteria was the presence of any corneal disease, history of ocular surgery or trauma, contact lens wear, pregnancy, or other ocular condition different than refractive error. One eye randomly selected from each participant was chosen. Each eye was examined by an experienced technician using three different Corvis ST devices, three times in each device. The measurements were taken alternately in each device in a random order in order to estimate between instrument variability and total reproducibility.

We analyzed the intraocular pressure (IOP) provided by the Corvis ST, the biomechanical compensated IOP (bIOP) [11,13] and the dynamic corneal response parameters (DCR): Maximum deformation amplitude (DA Max), Maximum deflection amplitude (DefA Max), DA ratio in 2mm[12] and DA ratio in 1mm, integrated Radius, Max Inverse Radius, first applanation (A1) Velocity and stiffness parameter at first applanation (SP A1).

An ANOVA model was used to assess the repeatability and reproducibility. It was built with random subject, random device and random interactions between subjects and devices as factors.

$Y_{ijk} = \mu + S_i + M_j + SM_{ij} + E_{ijk}$ with subject i=1..32; device j=1,2,3; repeat k=1,2,3

Repeatability of measurements refers to the variation in repeat measurements made on the same subject under identical conditions.

Reproducibility refers to the variation in measurements made on a subject under changing conditions, in this case the different devices[14]. Within subject Standard deviation (ζw) Coefficient of Variation (CV) and Coefficient of Repeatability (CR) were calculated from the random effects model. The CV is defined as the ratio of ζw to the overall mean. A lower CV is closely related to higher repeatability or reproducibility. The CR is the √2 x 1.96 ζw or 2.77 x ζw .The difference between two measurements for the same subject is expected to be less than 2.77 ζw for 95% of pairs of observations

Statistical analysis was accomplished with R Core Team (2016), a language and environment for statistical computing. (R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.)

## Results

The Male:Female rate was 1:1. The mean age was 37.3±11.7, ranging from 18.6 to 64.2 years.

Table 1 shows the values of ζw , CV and CR for repeatability and reproducibility derived from the random effects model for IOP, bIOP and DCR's.

Considering the pressure indices, the ζw was below 1mmHg for repeatability (0.98 for IOP and 0.89 and bIOP), the CV was 6.6% and CR 2.7 for IOP and 6.1% and 2.4 for bIOP. For reproducibility the ζw was around 1mmHg (1.12 for IOP and 1.05 for bIOP), the CV was 7.6% and CR 3.1 for

IOP and 7.1% and 2.9 for bIOP.

Most of DCR indices presented CV for repeatability below 4%. A1 velocity and SP_A1 had slightly higher CV 5.4% and 5%, respectively. For reproducibility the CV of most of the indices was below 6%. DAratio 1mm and Integrated Radius were below 4% (1.2% and 3.8%, respectively). A1 velocity and SP_A1 were slightly higher (7.9% and 6.5%, respectively).

## Discussion

The Corvis ST allowed a new perspective for the measurement of corneal biomechanics. The parameters obtained with the device have presented good realiability in virgin and post-PRK eyes. [15]. Repeatability was also good in normal and in keratoconic eyes. [16] New indices of DCR's have been developed and are showing good results in demonstrating biomechanical fragility of the keratoconic cornea. [17] They are part of a new display in the device, developed with a software upgrade in processing the signals. Since this is relatively new equipment, there are few studies assessing repeatability and reproducibility of its measures. To the best of our knowledge this is the first study to investigate the precision of these new variables. In this study we aimed to assess the repeatability and reproducibility of these new indices, along with IOP and bIOP.

In our study the repeatability and reproducibility ($\zeta w$ ) of IOP was very good, approximately 1mmHg (0.98 and 1.12, respectively). The CV was 6.6% and 7.6%, respectively, and the CR were also low below 3 mmHg for repeatability and around 3 mmHg for reproducibility. This is consistent with previous studies. Nemeth et al. found CV of 6.9% for the IOP repeatability[18]. Ali et al. found similar results to IOP repeatability with CV of 6.1%[19]. Bak-Nielsen et al. assessed not just repeatability but also reproducibility with measurements in different days[20]. In their study they found slightly lower values of CV, 4.2% for repeatability and 6.5% for reproducibility.

The bIOP is obtained with a method to measure the IOP in a way that it is less influenced by the stiffness of the cornea[13]. In *ex vivo* human eye globes, the bIOP was the closest measure to the true IOP. In *in vivo* studies it was less associated with corneal thickness and age.[11] The repeatability and reproducibility of this pressure in our study was similar to the IOP around 1mmHg (0.89 and 1.05, respectively). The CV was 6.1% and 7.2% and the CR was 2.4 and 2.9 for repeatability and reproducibility, respectively.

The DCR's presented good precision. The CV of repeatability and reproducibility for most of the indices were below 4% and 6%, respectively.

One of the first aspects that is noticed in the exam is the maximum amplitude of corneal deformation. It presented good repeatability, CV of 3.8% and reproducibility, CV 5.7%. It is consistent with other studies were the CV for repeatability ranged from 3.64% to 4.3%[18-20].

When we correct the maximum deformation amplitude for the whole eye movement we obtain the maximum deflection amplitude, which presented also good repeatability, CV of 3.7% and reproducibility, CV 5.3%. Bak-Nielsen et al. had also investigated the precision of this variable and found similar results, repeatability, CV of 4.4% and reproducibility, CV of 4.2%.

Five other new variables analyzed in this study (DAratio 2mm, DAratio 1mm, Integrated radius, Maximum inverse radius and SP A1) presented good precision[20]. The first four presented repeatability CV less than 4% and the reproducibility CV less than 5%. The SP A1 presented slightly higher repeatability and reproducibility CV (5% and 6.5%), this can be explained by the fact that it is a complex parameter that combines several information provided by the device.

The A1 Velocity was the DCR variable with higher repeatability and reproducibility CV (5.4% and 7.9%). In previous studies the repeatability CoV were much higher, ranging from 14.8% to 17.1%[18-20]. One study assessed the reproducibility CV and found also a higher value (13.5%).[20] The difference in the precision of this variable in our study was due to the new software that uses a Gaussian smoothing algorithm and allows more reliable measures of applanation velocity.

## Conclusion

The Corvis ST showed good precision (repeatability and reproducibility) for IOP measurements and for DCR parameters in healthy eyes.

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Table 1 – Corvis ST repeatability and reproducibility IOP and DCR indices.